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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	88066-5700	6851
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WINSTON & STRAWN LLP PATENT DEPARTMENT 1700 K STREET, N.W. WASHINGTON, DC 20006			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 01/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/692,123

Applicant(s)

LESCH, PAUL R.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13 and 15-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-13 and 15-32 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/30/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/12/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/12/2007 has been entered. Regarding the claims, claims 1, 5, 18, 28, and 31 were amended, and new claims 32-33 were added. Currently claims 1-7, 9-13 and 15-33 are pending for examination.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 9/12/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Drawings

The drawing of Figure 7 (5/30/2006) is objected to because the newly added injector (213) is shown in specific spatial relationship to the medicament cartridge, this is considered to be unsupported by the specification. As previously discussed the only disclosure to a jet injector, is in the first filed abstract (10/20/2000) in which "The present invention discloses a medicament cartridge for an injection device, such as a syringe or a jet injector." Therefore the spatial orientation of how the cartridge (212) is inside or how much is covered by the injector assembly (213) as disclosed in the submitted

drawing is unsupported by the original disclosure. Examiner suggests adding the injector a separate element adjacent the cartridge assembly (212). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-10, 12-13, 16-20, 22-27, and 30 are rejected under 35 U.S.C 102(b) as being anticipated by Schulter (4,968,302). Schulter discloses an automatic hypodermic syringe.

Regarding claim 1, 17, 18 and 30, Schluter et al. discloses a jet injector for highspeed injection (see abstract) of a medicament with a cylindrical tube (2), a first and second stopper, wherein the medicament (292) is between the stoppers (29, 22), and once triggered the first stopper pushes the second stopper through a needle (3) creating a fluid path for insertion into the body (Figures 1, 5A).

Regarding claims 2-6, 9-10, 12-13, and 16, Schluter et al. discloses that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figures 5A-5B). The needle has a bevel (34) of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 5A). The lumen of the tube is cylindrical and configured to fire via an injector system to expel the medicament (Figure 1).

Regarding claims 19-20, 22-27, Schluter et al. discloses an injection system in that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figures 5A-5B). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 5A).

Claim Rejections - 35 USC § 102

Claims 1-6, 9-10, 12-13, 16-20, 22-28, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wardlaw et al. (4,258,713).

Regarding claim 1, 17, 18, and 30-31, Wardlaw et al. discloses an injector (see abstract) of a medicament (14) with a cylindrical tube (2), a first and second stopper (10, 12), wherein the medicament is between the stoppers, and once triggered the first stopper pushes the second stopper through a needle (18) creating a fluid path for insertion into the body (Figure 1).

Regarding claims 2-6, 9-10, 12-13, and 16, Wardlaw et al. discloses that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figure 1). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 1). The lumen of the tube is cylindrical and configured to fire via an injector system to expel the medicament (Figure 1).

Regarding claims 19-20, 22-28, Wardlaw et al. discloses an injection system in that the movement of the stoppers (second stopper with an are that is designed for needle piercing) compresses the medicament through the needle that is fixed upon injection and second piercable stopper (Figure 1). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 11, 15, 21, and 29 are rejected under 35 U.S.C 103(a) as being unpatentable over Schluter et al. in view of Tanaka et al. (5,865,799). Schluter et al. meets the claim limitations as described above but does not include a third stopper, with a recess, and mixing of insoluble particles.

However, Tanaka et al. teaches a pre-filled syringe. Regarding claim 7, 11, 15, 21 and 29, Tanaka et al. discloses a third stopper, and an enlarged portion, that is used to mix particles prior to injection (Figures 1 and 5).

At the time of the invention, it would have been obvious to use the stopper system of Tanaka et al. with the system of Schluter et al. because the addition of a third stopper and enlarged portion allows for different drug combination doses to be injected. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Tanaka et al.

Claim Rejections - 35 USC § 103

Claim 32 is rejected under 35 U.S.C 103(a) as being unpatentable over Wardlaw et al. or Schluter et al. in view of Malay et al. (5,415,648). Wardlaw et al. or Schluter et al. meets the claim limitations as described above except for the stopper with the distal protrusion section.

However, Malay et al. teaches a multipurpose syringe.

Regarding claim 32, Malay et al. teaches an injector assembly (28) with a stopper (38) with a distal protrusion area (40) spaced away from the tube wall that is configured to be pierced by a beveled needle (23) (Figures 1-4).

At the time of the invention, it would have been obvious to add the stopper of Malay et al. to the systems of Wardlaw et al. or Schluter et al. in order to allow for quick stopper movement and easy needle puncture to create a liquid fluid path. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Malay et al. (cols 1-2).

Allowable Subject Matter

Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

The declaration under 37 CFR 1.132, filed 10/18/2007, is insufficient to overcome the rejection of claims 1-7, 9-13 and 15-32 based upon the references as set forth in the last Office action because: The declaration by the party at interest is used to supplement the original disclosure's lack of any specific definition of a "jet injector" and to provide a narrowed definition of the "jet injector", the declaration imparts specific characteristics of a jet injector which include:

"...These features include, for instance, a substantially more powerful and faster energy source and firing mechanism to drive the plunger when the injector is fired with a sufficiently elevated force and speed to generate the jet, a carefully dimensioned and configured jet nozzle to efficiently form the high speed jet, as well as a significantly more robust medicament container and supporting structure to contain the elevated pressures and withstand the shock produced by the rapid and powerful firing of the jet injector. Because of the high speed and pressure requirements for jet injectors, they are not powered by pressing directly on a plunger by hand, and the firing mechanism thus does not mimic a hand-powered injector."

Examiner contends that these features are absent, barring specific evidence, and are again unsupported by any element of the current disclosure of device. Examiner finds no support as to how Applicant's current invention is enabled to be used in a jet injector, by showing any of the characteristics above, which again are broad and nonspecific. MPEP 716.09 states that affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. In re Buchner, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). Additionally, affidavits or declarations purporting to

explain the disclosure or to interpret the disclosure of a pending application are usually not considered. In re Oppenauer, 143 F.2d 974, 62 USPQ 297 (CCPA 1944). Therefore since no specific definition was set forth and not apparent definitive structure is present, Examiner therefore follows the guidance in the MPEP 2106 to give all claims and terms within the claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Therefore the prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: see PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Date:

1/3/0



Christopher D. Koharski
AU 3763